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EXAMINER	
NAFF, DAVID M	
ART UNIT	**PAPER NUMBER**
1657	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

Office Action Summary	Application No.	Applicant(s)	
	10/540,936	KUHN ET AL.	
	Examiner	Art Unit	
	David M. Naff	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21 and 23-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21 and 23-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

An amendment of 7/11/08 amended claims 1, 3, 4, 6-9, 11, 14, 15, 17, 19 and 23-26, and canceled claim 22.

Claims examined on the merits are 1-21 and 23-26, which are all claims in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 and 23-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are unclear as to the form of the ceramic composite material by claim 1 requiring the nanoparticulate reinforcing material to comprise inorganic nanoparticles linked to one another, and not requiring anything that will link the nanoparticles together. The nanoparticles cannot link themselves together in the absence of something that causes linking. The claim is unclear how the nanoparticulate reinforcing material can be homogenously embedded in the ceramic substrate material, and nanoparticles of the reinforcing material be linked. Claim 1 is unclear how being formed from a nanoparticulate sol results in linked nanoparticles since steps of forming the linked nanoparticles from the nanosol are not set forth. Forming the linked nanoparticles from a nanosol is a process limitation, and to be clear as to the product of the process limitation, a complete process should be set forth. If a process limitation is required to define the composite, a product-by-process claim containing all steps for a complete process to form the composite should be set forth. Claim 1 is unclear how the nanoparticulate reinforcing material cross-links the substrate material. The mere presence of

the nanparticulate reinforcing material embedded in the substrate material will not cross-link the substrate. According to the specification (page 6 and claim 15), a slurry of ceramic powder or ceramic fibers (ceramic substrate material) is mixed with a biological material and an inorganic nanoparticle-containing nanosol (nanparticulate reinforcing material) capable of gelling, and gelling the nanosol to obtain the powder or fibers enveloped by the gel. This composite contains particles of the ceramic powder or ceramic fibers and the biological material embedded in the gel, and is not a composite of nanoparticles embedded in the ceramic substrate material since the ceramic substrate material is in the form of ceramic powder particles or ceramic fibers embedded in the gelled nanosol. Nanoparticles of the nanosol fuse together in forming the gel and discrete nanoparticles will not be available that can be linked and reinforce after gelling the nanosol. Claim 1 does not accurately claim a composite that is produced by the method described in the specification and the method required by claim 15. Claim 1 is inaccurate and unclear by requiring the additive or polymer to be embedded in the ceramic substrate material since the method described in the specification results in the additive or polymer embedded in a gelled nanosol containing embedded particles or fibers of the ceramic substrate material.

Claim 15 is unclear by not having antecedent basis in the steps of the method for “the at least one nanoparticulate reinforcing material (line 7), and “grains of the ceramic material” (line 9). The claim is unclear as to which component of previous method steps is the nanoparticulate reinforcing material, and the grains of the ceramic substrate material. The term “grains” is uncertain as to meaning and scope, and it is uncertain as to form and shape that is gains and not grains. The specification does not define grains. In line 6 of claim 15, requiring reinforcing the ceramic composite material is confusing since subsequently grains of the ceramic substrate are enveloped by a gel resulting from gelling a nanosol. It is unclear how nanoparticles of the nanosol can reinforce the composite since the composite is the gelled nanosol containing

enveloped grains of the ceramic substrate material. When cross-linking is given its art recognized meaning, the gel enveloping the grains does not cross-link the grains. Using reinforcing and cross-linking in a way different from their art recognized meaning and use leads to confusion and indefiniteness as to the invention claimed.

Bridging lines 7 and 8 of claim 15, requiring a "freeze-casting process" without setting forth steps of the process makes unclear how the process is functioning in the claim.

Claim 18 is unclear as to steps of reinforcing in a mold, and where in the reinforcing step of claim 15, the mold is used.

Claim 21 is unclear how the biocatalyst or biofilter differs from the ceramic composite material since structure of the biocatalyst or biofilter different from structure of the ceramic composite material is not defined.

Claims 23 and 24 are unclear as to difference in the "molded article" from the composite material of claim 1. Being molded requires a process of molding, and without the process steps used in the process, the form of the molded product is indefinite.

In line 2 of claim 25, "a freeze-casting process" should be replaced with --- the freeze-casting process --- since an alternative in claim 15 is a freeze-casting process.

In line 3, claim 25 does not have clear antecedent basis for "the biomaterial" and "the reinforcing nanosol". Claim 15 does not require a biomaterial and reinforcing nanosol.

Response to Arguments

The amendment urges that "reinforcing material" is defined in the specification. However, as set forth above, the process described in the specification results in a gel containing particles of ceramic powder or ceramic fibers enveloped by the gelled nanosol. It is not seen how nanoparticles of the nanosol reinforce the composite since the nanoparticles are in the nanosol before gelling, and the nanoparticles are not embedded in the ceramic substrate material since

the ceramic substrate particles or fibers are enveloped by the gel. After gelling the nanosol, discrete nanoparticles would not appear to exist due to the nanoparticles fusing together when gelling. It is suggested the invention be claimed only in terms of physical process steps performed as described in the specification.

The amendment urges that linking of the nanoparticles is by a gelling step. However, after gelling the nanosol, discrete nanoparticles would not appear to be present due to fusing together of the nanoparticles during gelling. If discrete nanoparticles remained after gelling, the nanoparticles may be only in physical contact with each other in the gel and not linked. The ceramic substrate powder particles or ceramic substrate fibers embedded in the gel may be only in physical contact with the gel, and only physical contact will not be cross-linking.

The amendment urges that there is no basis for requiring process limitations in the composition claims. However, claims to the composite material already require process limitations, and it is unclear how these process limitations define the composite material since a complete process is not set forth.

In regard to claim 21, the amendment urges that the composite material in its most elemental form can simply be the biocatalyst or biofilter. However, if this is the case, claim 21 does not further limit the composite material of claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims

was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-21 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuehn et al (DE 10065138) in view of Trieu et al (20020115742) and Bottcher et al (DE 19929616) and Wei et al (6,696,258).

The claims are drawn to a ceramic composite material comprising a ceramic substrate having homogenously embedded a biological material and a nanoparticulate reinforcing material. Also claimed is a method of making the composite by producing a slurry of the substrate and a dispersion of the biological material, adding to the slurry an inorganic nanosol capable of gelling, and carrying out neutralization or a freezing process to gel the nanosol and form the composite.

According to the present specification (paragraphs bridging pages 2 and 3 and pages 4 and 5), the present invention is a modification of ceramic moldings of DE 10065138 (Kuehn et al) by providing in the ceramic a nanoparticulate reinforcing material and biological material. The amendment states that claim 1 of Kuehn et al requires preparing a sol from a mixture of aluminum hydroxide or aluminium oxide fibers and an aqueous solution of sodium aluminate with an excess of base (NaOH), converting the sol to a gel with NaOH, freezing the gel to produce ice crystals, removal of solvent by thawing and drying to provide pores, removal of sodium ions and optionally sintering.

Trieu et al disclose bioactive nanocomposites containing a homogeneous mixture of a biocompatible polymer and a bioactive particulate ceramic (paragraph 0009). Pharmacological

agents can also be present (paragraph 0037). The particulate ceramic is in the form of nanoparticles (paragraphs 0053, 0054 and 0056), and acts to increase rigidity of the polymer (paragraph 0032).

Bottcher et al disclose a coating agent for protecting ceramics or glass against oxidation comprising a phosphorous silicate nansol formed by hydrolysis of metal alkoxides or metal halides and an acidic organophosphate solution (For example, see the title and abstract and page 3).

Wei et al disclose forming a sol-gel matrix mesoporous material (col 9, lines 25-53 and col 13, lines 47 to col 14, line 2). A base catalysis used in hydrolysis to produce the matrix can be a Group IA and Group IIA metal alkoxide (col 9, line 41). When a biologically active agent is provided in the matrix, neutralizing is carried out after hydrolysis before adding the biologically active agent (col 9, lines 54-67). The biologically active agent can be a microorganism (col 14, line 5).

When producing the gel of Kuehn et al, it would have been obvious to provide ceramic nanoparticles in the gel to increase rigidity of the gel as suggested by Trieu et al providing ceramic nanoparticles in a polymer to increase rigidity of the polymer. It would have been obvious to add the ceramic nanoparticles as a nanosol as suggested by Bottcher et al coating ceramics with a nanosol. The nanosol will obviously contain nanoparticles. Providing microorganisms as a biologically active agent to obtain the expected function of the microorganisms in the ceramic moldings of Kuehn et al would have been suggested by Wei et al providing microorganisms in sol-gel matrix since the ceramic molding of Kuehn et al is formed by a sol-gel process. When adding microorganisms, it would have been obvious to neutralize acid or base before adding the microorganisms as suggested by Wei et al.

Response to Arguments

The amendment urges that in Kuehn et al, the slurry is highly basic such that biological cells will not survive. However, some cells can survive at a very high pH. Moreover, it would have been obvious to lower the basic conditions to a point where desired cells can survive.

The amendment urges that Kuehn et al freeze after gelling, rather than using freezing to cause gelling. However, only claim 25 requires gelling by freezing. In regard to this claim, the claim does not exclude neutralizing when freeze-casting, and it would have been obvious in Kuehn et al to combine freezing and gelling with NaOH in a single step to simplify.

The amendment urges that in the invention, the ceramic substrate and reinforcing material are not highly basic, and the gel forming material is different from the ceramic substrate material. However, in claim 10, the ceramic substrate material can be aluminum oxide which is a material Kuehn et al can use to produce the sol. The present specification discloses (page 5, line 24) that the reinforcing material can be Al_2O_3. Therefore, in the claims the ceramic substrate and reinforcing material can be made of the same material and both can be nanoparticulate, and the claims do not exclude basic materials. In claim 15, neutralization is used for gelling and the claim does not limit the pH of neutralization.

The claims do not require covalent bonding between the nanoparticles of the gel, and do not exlude removal of sodium ions acid as in Kuehn et al.

The arguments concerning the disclosures of Trieu et al, Bottcher et al and Wei et al are noted. However, these references are applied with Kuehn et al, and when the references are considered in combination, the composite and method for its production presently claimed become obvious.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David M. Naff/
Primary Examiner, Art Unit 1657

DMN
11/8/08